



April 16, 2015

Ms. Monet Vela
Office of Environmental Health Hazard Assessment
Street Address: 1001 I Street
Sacramento, California 95814

Re: DARTIC Consideration to List
Bisphenol A on Proposition 65

Dear Ms. Vela,

The Infant Nutrition Council of America (INCA) is responding to the February 20, 2015 announcement by the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) that the Developmental and Reproductive Toxicant Identification Committee (DARTIC) will be meeting May 7, 2015 to consider the possible listing of Bisphenol A (BPA) based on female reproductive toxicity. The INCA is an association of manufacturers and marketers of formulated nutrition products, e.g., infant formulas and adult nutritionals, whose members represent over 95% of the infant formula purchased in the United States.*

The INCA supports OEHHA's efforts to protect its citizens from potentially harmful chemicals. The primary focus of the INCA and its member companies is and will always remain the health and welfare of infants and young children. The product we manufacture, infant formula, is the most highly regulated food in the world and continues to be the only safe, nutritious and recommended alternative to breast milk.

Although no infant formula manufacturer currently utilizes packaging in the U.S. that is formulated with BPA as a component of the product contact surface, we urge DARTIC not to recommend that BPA be listed under Proposition 65. Scientific consensus on potential health risks from BPA does not exist, and current evidence does not support labeling the presence of BPA on food packaging.

Consistent with this position, in November 2014, the U.S. Food and Drug Administration (FDA) reiterated its earlier perspective that, based on its most recent safety assessment completed in June, "BPA is safe in at the current levels occurring in foods. Based on DA's ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging."ⁱ

Other recent scientific studies continue to confirm that BPA is safe for use in food applications. In January 2015, the European Food Safety Authority's (EFSA) Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) published its Scientific Opinion on the risks to public health related to the presence of BPA in food. In conclusion, the panel stated there are no health concerns for any population, **including infants and young children**, from BPA at the current estimated levels of exposure (**emphasis ours**).ⁱⁱ This latest conclusion supports EFSA's past evaluations showing that BPA is safe.

In addition, international regulatory and health organizations have supported the safety of BPA:

- In December 2011, Food Standards Australia New Zealand (FSANZ) stated "the overwhelming weight of scientific opinion [regarding BPA] shows no human health and safety concerns at the levels people are exposed to."ⁱⁱⁱ

* INCA members are Abbott Nutrition, Mead Johnson Nutrition, Nestlé Infant Nutrition and Perrigo Nutritionals.

- In June 2011, a robust clinical exposure study funded by the U.S. Environmental Protection Agency and carried out by researchers from the FDA and the Centers for Disease Control and Prevention found that BPA concentrations in the blood are extremely low, including periods of high dietary exposure.^{iv}
- In November 2010, the World Health Organization, following an expert meeting to review the toxicological and health aspects of BPA, concluded that the “initiation of public health measures [to address BPA] would be premature.”^v
- Health Canada has conducted numerous surveys of BPA in foods and beverages, including infant formula, and repeatedly stated: “The current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including infants and young children,” and, “The nutritional benefits of baby food products far outweigh any possible risk.”^{vi}

Consistent with this approach, in 2009, DARTIC voted not to list BPA as a chemical known to cause reproductive toxicity. Further, OEHHA chose not to list BPA under Prop 65 following a January 2013 Notice of Intent to list the chemical.

Mandatory labeling of foods whose packaging contains BPA could be confusing to consumers and cause unnecessary alarm. Manufacturers are permitted to voluntarily label their products as not containing BPA, so consumers have the option to purchase such products if desired. In addition, mandatory labeling would create an undue burden on manufacturers and retailers, without benefitting public health and safety.

In summary, mandatory labeling on foods whose packaging containing BPA is not justified by the totality of the scientific evidence and does not provide any meaningful benefit to consumers. In fact, such labeling will likely have the opposite effect – creating confusion and unnecessary alarm. For these reasons, IFC urges the Developmental and Reproductive Toxicant Identification Committee not to recommend the listing of BPA on Proposition 65 during its upcoming May 7 meeting. Thank you for the opportunity to comment on this matter. If you have any questions, please contact me.

Sincerely,



Mardi K. Mountford, MPH
Executive Vice President

ⁱ U.S. Food and Drug Administration. Summary of FDA’s Current Perspective on BPA in Food Contact Applications. Last updated November 2014.

<http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm064437.htm#summary>

ⁱⁱ European Food Safety Authority, Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). Scientific Opinion on the risks of public health related to the presence of bisphenol A (BPA) in foodstuffs. EFSA Journal 2015;13(1):3978. <http://www.efsa.europa.eu/en/efsajournal/pub/3978.htm>

ⁱⁱⁱ Food Safety Australia New Zealand. Consumer Information on Bisphenol A. December 2011. <http://www.foodstandards.gov.au/consumerinformation/bisphenolabpa/>

^{iv} Teeguarden JG, et al. 24-Hour Human Urine and Serum Profiles of Bisphenol A During High Dietary Exposure. Toxicological Sciences (2011). <http://toxsci.oxfordjournals.org/content/early/2011/06/24/toxsci.kfr160>

^v World Health Organization. Summary of November 2010 Expert Meeting to Review the Toxicological and Health Aspects of BPA. http://www.who.int/foodsafety/chem/chemicals/bisphenol_release/en/index.html

^{vi} Health Canada, Bureau of Chemical Safety, Food Directorate. Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature. December 2009. <http://www.hc-sc.gc.ca/fn-an/pubs/securit/summ-bpa-temp-eng.php>